Opening Statement of the Honorable Fred Upton
Subcommittee on Health
Hearing on "21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients"
June 11, 2014

(As Prepared for Delivery)

We launched the 21st Century Cures initiative with the goal of accelerating the discovery, development, and delivery of innovative new treatments and cures to patients, ensuring that the United States remains the biomedical innovation capital of the world. 21st Century Cures aims to close any gaps between the science of cures and how we regulate those therapies. This must be an ongoing conversation.

Today we will hear testimony about whether our current legislative and regulatory framework encourages innovators to pursue the development of drugs and devices that are crucial to helping our nation's patients. I am proud of the fact that this committee recently came together on a bipartisan basis to address this innovation gap in the context of antibiotics. But, it is clear that our work is far from over.

We lack effective treatments for almost 95 percent of the known diseases affecting patients today and over 95 percent of drugs in development do not make it to market. In addition to working with FDA and others to decrease the time and cost it takes to bring new products to patients, we must heed the advice of the President's Council of Advisors and take a fresh look at current and potential economic incentives to promote innovation. As we have seen in the context of orphan diseases and most recently for antibiotics, periods of market exclusivity are powerful tools for us to consider in ushering in the next generation of treatments and cures.

This is certainly a balancing act, and I am committed to pursuing any such changes only after engaging in a thorough and thoughtful dialogue with all interested stakeholders, which is precisely why we are here today.

The Hatch-Waxman Act is an enduring piece of legislation that will undoubtedly form the basis for any such conversation. I agree with Senator Hatch who recently stated, "The foundation laid by the Hatch-Waxman Act thirty years ago will continue to be the mechanism by which the government incentivizes development of lifesaving drugs" but we do have "an obligation to periodically reevaluate how the balance can be adjusted to account for the sweeping changes in the broader health care sector."

The time and cost of bringing an innovative product to market today is much different than it was in 1984, and yet under Hatch-Waxman, the same baseline exclusivity period is still granted to new drugs. We have an opportunity today to assess whether we still have the right balance in place - particularly for products meeting unmet medical needs.

We also have an opportunity to hear about incentives for new devices. This committee has worked with FDA and stakeholders to help make the regulation of devices more predictable and consistent, but it is clear that we must continue our collaboration to not only improve FDA but also coverage and reimbursement.

In closing, I want to thank those folks who have responded to our call for input in this 21st Century Cures initiative – we appreciate the thoughtful contributions, especially the responses from everyday Americans. Please continue to share your ideas with cures@mail.house.gov. Working together, we will make a difference.

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